effects on events, they may be important. The notes further state that, "This lack of effect may be advantageous for the reparative process that follows plaque ulceration." This effect was linked to stabilizing the plaque's fibrous cap against rupture.

116. In an email, "Pravachol District Plan for 2002, From: Annette Harding, dated Jan. 8, 2002," reprints were referenced as part of the business plan. These particular reprints were used due to their utility in selling Pravachol based on off-label uses. The following reprints were specifically referenced: LCAD, PTT, Byington, and Multinational, and the following message: stabilize the plaque and use reprints Lamm and Rosenson to promote the message.

117. A reprint entitled, "Hyperlipidemia and Coronary Disease," by Lucie Lacoste, PhD, Jules Y. T. Lam, MD, et al. (Known in BMS as the Lamm or Lam study or rarely as the Lacoste study), was knowingly disseminated by BMS without solicitation to physicians in order for physicians to make clinical treatment decisions based on off-label and misleading information. Entire conclusion section of this reprint speaks to pravastatin's effect on platelet thrombus formation as a reason for CV event reduction. This reprint was very important in setting up the doctor to believe that by lowering cholesterol you lower thrombus formation. The idea that hypercholesterolemia leads to hyperactive platelets and increased thrombus formation was easy to get buy in from the doctor on because they were led to think high cholesterol equals high thrombus formation risk by this paper and the BMS spin. BMS claimed that any statin that lowered cholesterol would have a similar effect on thrombus formation, i.e., decrease it. It was very important to get physician buy in on this point, and then present another abstract by Dr. Lacoste and Dr. Lam from the February 1996 JACC (Journal of the American College of

Cardiology), to sell Pravachol's impact on ancillary mechanisms versus simvastatin (Zocor).

118. Abstract #1045-19 from JACC 1996, entitled, "Comparative Effect of Pravastatin and Simvastatin on Platelet-Thrombus Formation in Hypercholesterolemic Coronary Patients," by Lucie Lacoste PhD, Jules Y.T. Lam MD, was used by BMS without solicitation to influence physicians to make clinical treatment decisions based on misleading and off-label information. After getting the doctor to agree that decreasing cholesterol would decrease thrombus formation, BMS sales representatives would pull out this abstract and show that whereas there was again strong inhibition of thrombus formation with pravastatin, the same was not found with simvastatin (Zocor). The quote at the end of the abstract was used all the time by BMS representatives to drive home the point to physicians that pravastatin had "other mechanisms" to affect CV events, especially versus simvastatin. This quote states: "Thus, both Simva and Prava decreased serum total and LDL cholesterol, but platelet thrombosis was inhibited more by Prava at both the high and low shear rates tested. These results suggest that after 2-3 months of therapy, HMG-CoA reductase inhibitors may have a differential effect on platelet thrombosis which may influence the early clinico-pathologic evolution of the atherosclerotic process."

119. Additional reprints were also regularly used by BMS without solicitation from doctors to promote the BMS off-label message regarding the alleged anti-thrombotic and anti-platelet effects of Pravachol as well as to provide information about the "other mechanisms" of Pravachol that allegedly reduced CV events that were off-label and misleading. These additional reprints included the following: "Antiatherothrombotic

Properties of Statins, Implications for Cardiovascular Event reduction" by Robert S. Rosenson MD, et al. (Known in BMS as the Rosenson study); "Beneficial Effects of Pravastatin … L-CAD Study" by Hans-Richard Arntz MD, et al. (Known in BMS as the L-CAD study); "Effects of Pravastatin in Patients with … Risk Factors" by The Pravastatin Multinational Study Group for Cardiac Risk Patients. (Known in BMS as the Multinational study); "Pravastatin Limitation of …Clinical Events" by Bertram Pitt MD, et al. (Known in BMS as the PLAC I study); "Effects of pravastatin on mortality…cholesterol levels" by J. Simes, et. al (Known in BMS as the PPP or Pravastatin Pooling Project study); "Long-term Effects of Pravastatin on Plasma Concentration of C-reactive Protein" by Paul M. Ridker MD, et al. (Known in BMS as the Ridker study); "Pravastatin Therapy in Hyperlipidemia:… Hemostatic Proflie" by George Dangas MD, et al. (Known in BMS as the Dangas study).

120. All of the above-listed reprints, abstracts and letters of abstracts were regularly used nationwide by BMS representatives, without receiving a solicitation or request from a physician, to promote Pravachol based on off-label and misleading information contained in those materials (including disseminating off-label and misleading information that was prohibited by FDA regulations as well as the DDMAC letter of January 26, 1998) and to influence clinical treatment decisions by physicians to prescribe Pravachol for off-label purposes. BMS representatives had a binder with reprints and other off-label and misleading information about Pravachol that were used as part of BMS's off-label scheme to promote Pravachol. This scheme was carried out by BMS systematically with the intent to cause the submission of false or fraudulent claims for reimbursement from federal and state governments for Pravachol prescriptions that were made as a result of

the off-label and misleading information provided by BMS to doctors and health care providers.

D. Implementing the Off-Label Scheme Through National and Regional Business Plans

121. BMS developed business plans to implement its off-label strategy to market Pravachol. For example, the Florida Region 2001 Business Plan (Oct. 23, 2000) noted the following:

> -- one of the internal (which means BMS controlled) microenvironmental factors was Pravachol's "Secondary mechanism of action" and the need for MOA (mechanism of action) differentiation by sales reps. Also noted is the preferred status of Pravachol on Medicaid PDL (preferred drug list), which made it easier for MDs to prescribe for their Medicaid patients.
>
> -- the Pravachol message was time consuming and complex. This was the off-label MOA messaging. It also notes the added support of the CMRS sales force.
>
> – there was an opportunity to "Capitalize on cutting edge science to expand population eligible for treatment – i.e. HSCRP and Pravachol"
>
> -- Pravachol market share was dropping over 9/1999 – 8/2000, while Zocor and Lipitor shares were increasing. During this time period, the market and U.S. Government guidelines (NCEP) were stressing lower LDL-C was better for CV event reduction. This put Pravachol at a marketing disadvantage because it was less potent than Zocor or Lipitor in LDL-C reduction.
>
> -- CMRS would help with Cardiology coverage. Also notes a strength for reps were the Prove-It and Prince trials. Prove-It was not published until 2004, but was used to string along prescribers in that BMS would "prove" that Pravachol's other mechanisms of action provided CV event reduction equal to or better than Lipitor.
>
> -- market place threat was "Lower is Better" mindset.
>
> -- one issue was reps inability to differentiate the value of Pravachol, lower is better, class effect.
>
> -- Faxbacks as tactics for selling impact, to disperse off-label info.
>
> -- training initiative to assure reps knew Pravachol message which included clear differentiation points. These were about mechanisms of action supposedly unique to Pravachol.

-- 1.7 million Medicaid patients live in Florida as a prime opportunity for BMS product use.

122. This reinforced BMS's nationwide promotion of Pravachol through the use of off-label and misleading information.

123. Between 1999 and 2003, BMS regularly targeted key or high prescribing doctors with Medicaid patients, with the off-label and misleading information about Pravachol.

124. For example, in an email dated Nov. 14, 2000, Subject: Top 15 Medicaid Prescribers by state and by district, From: Diana M. Schmidt, there were multiple references to specific physicians that the Relator remembers were given the Pravachol off-label promotion to persuade the doctor to prescribe Pravachol. These physicians stand out as key doctors and the sales reps made multiple calls to these doctors. Relator has first hand knowledge and personally witnessed the off-label and misleading information disseminated to these doctors at the direction of BMS. These doctors were actively promoted the off-label mechanism of action as the reason to use and continue to use Pravachol for CV event reduction versus other statins.

125. In the 2001-2002 time frame, a BMS slide deck entitled "East Region CMRS 90 Day Action Plan," was distributed within BMS CMRS sales regions throughout the eastern United States. This slide deck included information that was designed to "Maximize Medicaid Opportunities" for Pravachol and noted Medicaid Pravachol segment opportunities as well as the multiple ways that CMRS had a very intense focus on Medicaid prescribers. This involved identification, increased calls and other activities to impact their business. The CMRS sales team routinely used the off-label Pravachol promotional message, especially because they were "specialists" and had intense training and resources that pushed the off-label message for Pravachol.

126. In an email dated Jan. 11, 2002, Subject: Meeting Followup, From: Diana M. Schmidt, who was the Govt Affairs rep, responsible for Medicaid business, noted a list of the Community Health centers in Florida and the team alignment. This email shows who was responsible for the business generated in these clinics which are funded to a large degree by Medicaid as most of the patients are indigent and get their prescriptions filled by Medicaid. The Relator has personal knowledge of and witnessed sales calls on the Collier Health Service Clinic in Immokalee, Fl. On more than one occasion, the Relator witnessed the sale of Pravachol on the off-label claims of other mechanisms of action for CV event reduction using many of the unapproved resources based on off-label and misleading information. The clinic physician agreed to prescribe Pravachol for their Medicaid patients based on this misleading promotional message and off-label data.

127. Relator also has personal knowledge that the off-label and misleading information to sell Pravachol was targeted to physicians who prescribed Pravachol to patients whose prescriptions were paid for or reimbursed through Medicaid, Medicare and other government programs, and that this activity by BMS occurred nationwide.

E. Use of Unsolicited Fax Backs to Disseminate Off-Label and Misleading Information.

128. Faxbacks consisted of extra, "off-label," manufacturer information regarding certain products. These were not to be sent proactively, instead, only as a reply to a doctor's unsolicited request for off-label information.

129. However, Defendant BMS consistently ignored this rule and pressured doctors into accepting the faxbacks as part of BMS's off-label strategy.

130. The following BMS Pravachol Faxbacks were routinely used proactively (without unsolicited requests by the provider) by BMS to promote Pravachol:

-- PRAV02 is Mechanisms of Action In Reducing the Risk for Cardiovascular Events, in Addition to Lowering Cholesterol.

-- PRAV03 is PRAVACHOL versus Other HMG-CoA Reductase Inhibitors in Reducing Cardiovascular Events.

-- PRAV13 – Influence of PRAVACHOL and Plasma Lipids on Clinical Events in the West of Scotland Coronary Prevention (WOSCOPS Study Group, 1988), Publication. This is the "Quintile Analysis" or WOSCOPS reanalysis that was discussed as "misleading" in the DDMAC letter of January 26, 1998.

-- PRAV26 – Prove-It study. Information on the Prove-It study from 2003, although Prove-It was not published until 2004.

131. All of these Faxbacks contained off-label information and were routinely, proactively used by reps to send prescribers off-label information, including (PRAV13) information DDMAC specifically said was misleading.

132. BMS Performance Expectations for sales reps, included under the category "Territory Management" and "Resource Optimization," the specific behavior expected for each rep to "[r]outinely and effectively use[] Fax Back Program … and other non-personal promotion." The use of faxbacks and provision of off-label information was also documented in "Advance Books" that were used to document representative and sales manager performance against national performance expectations. In addition, at the regional level, the BMS Florida region director required use and had use tracked at the region level to assure sales reps were sending Faxbacks to doctors. This was documented in the Florida Region 2001 Business Plan (Oct. 23, 2000) as follows: – Faxbacks to be used as tactics for selling impact, to disperse off-label information; District Managers were to "Drive utilization of Faxbacks"; and the region wanted monthly tracking of how many Faxbacks were being sent out.

F. Results of the BMS Off-Label Marketing and Misbranding of Pravachol

133. Most or all of the uses that Pravachol was promoted for as listed in paragraph 80, *supra.*, are not and have never been in its FDA-approved labeling. While Pravachol was promoted for CV event reduction, these other mechanisms were presented as the reason it was able to reduce CV events, independent and separate from cholesterol reduction. This was done during a period when more and more data was showing that lowering LDL and total cholesterol was more beneficial to patients for decreasing CV events. Pravachol was at a clear disadvantage in the market during these years and BMS knowingly and deliberately used misleading and off-label data to sway doctors to continue to prescribe Pravachol or begin prescribing Pravachol. As previously mentioned, the PROVE-IT trial was paraded to doctors for years before it was completed or published as proof that BMS was standing behind these ancillary mechanisms. Several times over the years the Relator heard at meetings that PROVE-IT was going to take BMS almost to the end of the Pravachol patent and just by doing the study, and regardless of the study's outcome, BMS was keeping many doctors from switching from Pravachol to another statin as they awaited the results just by participating in the study. When finally published in 2004, the results of PROVE-IT showed that lower LDL and total cholesterol were better for CV event reduction than more moderate reductions seen with Pravachol and that patients who were given Pravachol over another drug had a significantly higher amount of CV events.

134. BMS intentionally violated the ban on disseminating off-label and misleading information. 21 U.S.C. §360aaa-6; 21 U.S.C. §§ 360aaa(b) & (c) and 360aaa-1; 21 C.F.R. §§ 99.1(b); 99.3(g); 99.3(i)(5); 99.101(a)(3)-(1)(5); 99.101(b)(1)-(b)(2); 99.103(a)(1)-(a)(4)(i).

135. Additionally, BMS's promotional claims recommending or suggesting Pravachol for a use other than that for which FDA has reviewed safety and effectiveness data created a new "intended use" for which adequate directions must be provided in product labeling. 21 U.S.C. §352(f)(1); 21 CFR 201.5, 201.100, 201.128. Absent such directions, Pravachol is misbranded under Section 502(f)(1) of the misbranding statute. 21 U.S.C. § 352(f)(1). BMS knowingly and deliberately violated the misbranding statute in its off-label promotion of Pravachol.

136. Defendant sold hundreds of millions of dollars worth of Pravachol and generated more than $600 million in Medicaid sales from 1999 to 2003 alone, the most of which was sold as a direct result of BMS's illegal off-label marketing. For example, according to data published by the Centers for Medicare and Medicaid Services ("CMS") of the U.S. Department of Health and Human Services, Medicaid filled 972,898 prescriptions for Pravachol at a total cost of $79,556,848 in 1998, and 1,609,773 prescriptions for Pravachol at a total cost of $191,149,058 in 2003.

137. Based on the Relator's first hand knowledge during the years 1999 to 2003 most of the sales of Pravachol were made because of the misleading and off-label information that BMS presented to doctors and health care providers.

138. Mr. Richardson personally observed and witnessed BMS sales representatives on countless sales calls presenting the misleading and off-label information to doctors and health care providers, and doctors and health care providers confirming that they would prescribe Pravachol in preference over other statins based on the off-label and misleading information provided by BMS, during the 1999-2003 time frame in the states of Florida, Georgia, Maryland, Virginia and the District of Columbia. BMS sales representatives

would actually close the sales calls by asking the doctors and health care providers if they would prescribe on the basis of the off-label and misleading promotional BMS message. It was a basic BMS management expectation for sales representatives to close sales calls, which entails asking the physician to prescribe the product based on the information presented during the call. Mr. Richardson observed the off-label and misleading information presented on BMS sales calls and asking physicians to make a commitment to prescribe Pravachol for the off-label and misleading reasons during this time frame.

139. Mr. Richardson also personally reviewed during his employment with BMS Pravachol sales data for the 1999-2003 time period showing that physicians and health care providers actually submitted false claims to the federal and state governments for reimbursement under Medicaid, Medicare, and other government programs as a result of the off-label and misleading information provided by BMS to those physicians and health care providers.

140. At the time BMS knowingly presented off-label and misleading information to physicians and health care providers, BMS was aware that those physicians and health care providers would sign a certification that they were in compliance with all laws and regulations applicable to the Medicaid program, including the ban on off-label promotion and misbranding, in order to seek reimbursement for the Pravachol prescriptions. By agreeing to prescribe Pravachol based on the off-label and misleading information, which violates the laws prohibiting off-label marketing and misbranding, those doctors and health care providers would be violating those certifications or submitting false certifications.

141. All of the above-referenced conduct was carried out nationwide by BMS to promote Pravachol based on off-label and misleading information contained in material that was disseminated by BMS (including information that was prohibited by FDA regulations as well as the DDMAC letter of January 26, 1998). BMS engaged in these activities knowingly and deliberately with the intent to influence clinical treatment decisions by physicians. As a result of this scheme BMS did in fact improperly influence clinical treatment decisions and cause the submission of false or fraudulent claims for reimbursement from federal and state governments for Pravachol prescriptions that were made as a direct result of the off-label and misleading information provided by BMS to doctors and health care providers. But for BMS's improper off-label marketing tactics Pravachol would not have been prescribed by those doctors who received the off-label information, or alternatively, reimbursement for those Pravachol prescriptions would not have been approved by federal and/or state governments who were not aware that BMS was promoting the sale of Pravachol through the dissemination of off-label and misleading information.

COUNT I

(False Claims Caused By Knowing Promotion of Prescription Sales Ineligible for Medicaid or Medicare Reimbursement)

142. The allegations contained in the above paragraphs are hereby re-alleged and as set forth fully above.

143. This is a claim for treble damages and penalties of each false claim and each false statement under the False Claims Act, 31 U.S.C. §3729, *et seq.*, as amended.

144. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

145. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Government to approve and pay such false and fraudulent claims.

146. Each prescription that was written as a result of Defendant's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for such off-label or illegally induced prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

147. Defendant BMS has knowingly caused the submission of tens of thousands of false claims by knowingly promoting to Medicaid and/or Medicare providers sales of Pravachol for off-label uses which were not eligible for Medicaid or Medicare reimbursement. Every prescription for each of these pharmaceuticals which was not written for medically acceptable use that was submitted to Medicaid and/or Medicare, constitutes a false claim. Defendant BMS is liable, pursuant to 31 U.S.C. §§ 3729(a)(1) and (a)(2), for each of those false claims which would not have been written but for Defendant's off-label promotion of Pravachol. At the time Defendant BMS engaged in such unlawful promotional activities, it knew that off-label promotion to prescribe Pravachol was ineligible for Medicaid and/or Medicare and other government reimbursement and the Defendant's activities would, in fact, cause numerous ineligible prescriptions to be submitted to Medicaid and/or Medicare or other government reimbursement programs. Had Defendant BMS not engaged in such promotions, federal

funds would not have been used to pay for prescriptions that were not qualified to be reimbursed by Medicaid and/or Medicare or other government programs.

148. In order to cause ineligible claims to be submitted to Medicaid, Medicare or other government programs, Defendant BMS engaged in a systematic and extensive course of fraudulent conduct. This conduct included, *inter alia,* deliberate disregard of FDA regulations concerning off-label promotion and misbranding (and conduct designed to hide such disregard from the regulatory authorities); deliberate disregard of the DDMAC letter of January 26, 1998; deliberate misrepresentations to physicians of the evidence regarding the safety and efficacy of off-label usage of Defendant's products; the improper use of fax backs; and other misconduct. In addition, BMS made deliberate payment of tens of thousands of kickbacks to encourage physicians to order Defendant's products, including Pravachol.

149. Plaintiff-Relator cannot identify at this time all of the false claims which were caused by Defendant BMS's conduct. Plaintiff-Relator has first-hand knowledge that physicians and health care providers were presented with the off-label and misleading information by BMS with the intent that these doctors and health care providers submit claims for reimbursement of the Pravachol prescriptions based on that false information. The false claims were presented by thousands of separate entities across the United States, and over several years. While many of the false claims were submitted by physicians, pharmacists and other providers with whom the Plaintiff-Relator has had no dealings and the records of the false claims are not within the Plaintiff-Relator's control, some of the false claims were submitted by doctors and health care providers with whom Plaintiff-Relator had first hand dealings or whom Plaintiff-Relator witnessed being subjected to the off-label

and misleading information by BMS. Additionally, Plaintiff-Relator has first hand knowledge that doctors and health care providers did submit false claims for reimbursement of Pravachol based on the off-label and misleading information provided by BMS. Specification of the vast number of false claims would be burdensome to the Court and the parties and given the vast number of false claims, their broad scope and complexity, Plaintiff-Relator is excused from the requirement of specifying each false claim as he has no control over the entities and therefore no access to the records in their possession that document these false claims. The time period of the false claims was from approximately 1998, and extending through 2003. Such claims were made across the United States resulting from BMS's nationwide off-label scheme.

150. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by Defendant, paid the claims that would not have been paid but for Defendant's illegal off-label marketing practices and illegal inducements.

151. As a result of Defendant BMS's actions, the United States has been damaged in an amount to be determined at trial. The United States has paid directly or indirectly tens of thousands of false claims and spent hundreds of millions of dollars on prescriptions for medications unnecessarily, for off-label prescriptions that were not approved by the FDA, and for prescriptions that were illegally induced as a result of Defendant's fraudulent conduct. Congress, the federal government, and the individual states, never intended to make such payments and would have never made such payments but for the conduct of Defendant. Although Defendant BMS did not submit the claims directly and did not directly receive Medicaid payments from the states and the United States, Defendant BMS has been the greatest beneficiary from this pattern of unlawful conduct, filling tens

of thousands of prescriptions for Pravachol which would never have been placed but for the Defendant's unlawful conduct.

152. Plaintiff-Relator is entitled to an award of expenses, attorneys' fees, and costs in an amount to be determined by the Court under 31 U.S.C. §3730(d).

COUNT II

(Claims for Expenses, Attorney's Fees and Costs for Claims that Were Settled)

153. The allegations contained in the above paragraphs are hereby re-alleged and as set forth fully above.

154. In the order approving the settlement and dismissing some of the Plaintiff-Relator's original claims pursuant to the settlement, the Court retained jurisdiction to decide issues concerning Relator's expenses, attorneys' fees, and costs under 31 U.S.C. §3730(d). Additionally, dismissal was without prejudice as to Plaintiff-Relator's claims for expenses, attorney's fees and costs and BMS's right to challenge or seek dismissal of Plaintiff-Relator's claims for expenses, attorney's fees and costs.

155. Pursuant to the Settlement Agreement entered into among the United States of America, several Relators (including Mr. Richardson) and Defendant BMS and Apothecon, BMS agreed to pay to the United States the sum of three hundred seventeen million, four hundred thirty-six, and eighty-one dollars ($317,436,081), plus interest, to resolve alleged violations of the False Claims Act. A portion of this amount was allocated to Mr. Richardson for a Relator's share pursuant to the *qui tam* provisions of the False Claims Act.

156. The portion of the federal payment under Settlement Agreement that was based in part on Plaintiff-Relator's allegations related to contentions, made by Plaintiff-Relator, other

Relators and the U.S. Government that, during the period from January 1999 through December 2003, BMS knowingly and willfully offered and paid illegal renumeration to physicians, and to some physician assistants and nurse practitioners, through consulting fees and expenses for participating in National Consulting Conferences, Regional Consulting Conferences, Clinical Advisory Councils, District Advisory Boards, Interactive Training Sessions, Preceptorships, and similar consulting programs, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2). Mr. Richardson, other Relators and the U.S. Government also further contended that, during this time period, BMS knowingly caused the submission of false and/or fraudulent claims to Medicaid, Medicare, other federal health care programs, and caused DVA and the DOD to purchase BMS drugs, by inducing these physicians, physician assistants, and nurse practitioners to prescribe and/or to recommend the prescribing BMS drugs.

157. Plaintiff-Relator is entitled to an award of expenses, attorneys' fees, and costs in an amount to be determined by the Court under 31 U.S.C. §3730(d), for substantially prevailing on his claims that were settled.

COUNT III

(Arkansas Medicaid Fraud False Claims Act; Ark. Code Ann. § 20-77-901 et seq.)

158. The allegations contained in the above paragraphs are hereby re-alleged and as set forth fully above.

159. This is a claim for treble damages and penalties under the Arkansas Medicaid Fraud False Claims Act.

160. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Arkansas State Government for payment or

approval.

161. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Arkansas State Government to approve and pay such false and fraudulent claims.

162. The Arkansas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal off-label marketing practices and illegal inducements.

163. By reason of the Defendant's acts, the State of Arkansas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

164. The State of Arkansas is entitled to a penalty of not less than $5,000 and not more than $10,000 for each and every violation or false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT IV

(California False Claims Act; Cal Govt Code §12651(a)(1) and (2))

165. The allegations contained in the above paragraphs are hereby re-alleged and as set forth fully above.

166. This is a claim for treble damages and penalties under the California False Claims Act.

167. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

168. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the

California State Government to approve and pay such false and fraudulent claims.

169. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid the claims that would not have been paid but for Defendant's illegal off-label marketing practices and illegal inducements.

170. By reason of the Defendant's acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

171. The State of California is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT V

(Delaware False Claims And Reporting Act; 6 Del C. §1201(a)(1) and (2))

172. The allegations contained in the above paragraphs are hereby re-alleged and as set forth fully above.

173. This is a claim for treble damages and penalties under the Delaware False Claims And Reporting Act.

174. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

175. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

176. The Delaware State Government, unaware of the falsity of the records, statements and

claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal off-label marketing practices and illegal inducements.

177. By reason of the Defendant's acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

178. The State of Delaware is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT VI

(Florida False Claims Act; Fla. Stat. Ann. §68.082(2))

179. The allegations contained in the above paragraphs are hereby re-alleged and as set forth fully above.

180. This is a claim for treble damages and penalties under the Florida False Claims Act.

181. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

182. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

183. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal off-label marketing practices and illegal inducements.

184. By reason of the Defendant's acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

185. The State of Florida is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

COUNT VII

(Georgia State False Medicaid Act; Ga. Stat. § 49-4-168 et seq.)

186. The allegations contained in the above paragraphs are hereby re-alleged and as set forth fully above.

187. This is a claim for treble damages and penalties under the Georgia State False Medicaid Act.

188. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

189. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

190. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal off-label marketing practices and illegal inducements.

191. By reason of the Defendant's acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.